

## **Remarks/Arguments**

### **Status of Claims**

Claims 1 and 3-16 are pending and under substantive examination. Claims 1, 3-9 and 11 are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 12-16 have been determined to recite allowable subject matter.

Claim 10 is rejected.

### **Claim Amendment(s)**

Claim 10 has been amended to recite:

An isolated and purified rhesus dickkopf-1 (rhDkk-1) polypeptide comprising *the* sequence of amino acids as set forth in SEQ ID NO:2.

Support for this amendment can be found on page 4, lines 25-27 of the specification (as published in WO2005/049640, on June 2, 2005).

### **The Rejection of Claim 10 under 35 USC §102(e) Should be Withdrawn**

The Office Action indicates that claim 10 is rejected under 35 USC §102(e) as being anticipated by US Patent No.: 7,057,017 (Millennium Pharmaceuticals, Inc.) (referred to herein as the '017 patent).

Claim 10 of the instant application is directed to an isolated and purified rhesus monkey dickkopf-1 (rhDkk-1) polypeptide comprising the sequence of amino acids set forth in SEQ ID NO:2. The Office Action indicates that recitation of the limitation "a sequence of amino acids as set forth in SEQ ID NO: 2" is "anticipated by any sequence, even as short as two consecutive amino acids, that is found in SEQ ID NO:2. "

The Office Action indicates that '017 patent teaches a dkk-related polypeptide (SEQ ID NO:8) that is 98.5% identical to SEQ ID NO:2 of the instant application, as supported by a sequence alignment set forth on pages 3-4 of the Office Action. Based on this observation, the Examiner concludes that the prior art polypeptide comprises many sequences as set forth in SEQ ID NO:2. This statement is supported by, "for example, the polypeptide comprising amino acids 85-138 of SEQ ID NO:8 recited in claim 5 of the '017 patent, which is 100% identical to the corresponding sequence in SEQ ID NO:2.

As indicated above Claim 10 has been amended to recite:

An isolated and purified rhesus dickkopf-1 (rhDkk-1) polypeptide comprising *the* sequence of amino acids as set forth in SEQ ID NO:2.

In light of the amended claim language, the anticipation rejection based on US Patent No.: 7,057,017 has been obviated. This statement is supported by the sequence alignment included in the Office Action which supports the conclusion that the prior art sequence does not include each and every element of the claimed subject matter. More specifically, the amino acid sequence of the prior art Human dkk-related protein sequence does not deprive the Rhesus monkey dkk-1 protein of the invention of its novelty, because the human and rhesus proteins do not share 100% identical amino acid sequences.

On page 3 of the Office Action, the Examiner states that "the recitation of an origin, rhesus, indicates a process for isolation of the claimed product. The courts have established that if a claimed product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process (internal citations omitted).

Applicants respectfully disagree with the Examiners characterization of Claim 10 as a "product-by-process" claim, as a consequence of reciting the term "rhesus." Typically, product-by-process claims are claims in which the product is defined, at least in part, in terms of the method or process by which it is made. The original purpose of product-by-process claims was to allow inventors to claim an otherwise patentable product that resists definition by other than the process by which it is made.

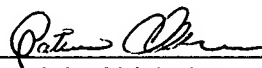
In contrast Claim 10 recites a specific amino acid sequence (set forth in SEQ ID NO:2) to define the structure of the claimed subject matter. Accordingly, there is no need to define the product (e.g. rhDKK-1) by the process by which it is made. The characterization of Claim 10 as a "product-by-process" claim is also inconsistent with the fact that Claim 10, in both its original and amended form, does not recite any limitations that can be construed as step (i.e. process limitations). The term "rhesus" is recited in the claim to identify the source of the polypeptide, which serves the purpose of distinguishing the claimed subject matter from the prior art and defining the subject matter that Applicants regard as their invention.

In light of the amended claim language, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection of Claim 10 under 35 USC §102(e) as being anticipated by the '017 patent.

**CONCLUSION**

In light of the claim amendments and remarks set forth above, Applicants believe that they are entitled to a Letters Patent, and respectfully request that the Examiner expedite prosecution of the application to issuance. Should the Examiner have any question, he is encouraged to telephone the undersigned.

Respectfully submitted,

By   
Patricia Chisholm  
Reg. No. 45,822  
Attorney for Applicant

MERCK & CO., INC.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
(732) 594-5738

Date: June 26 , 2008